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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,495	01/15/2004	James H. Silver	JSILVER.1CP2CP	6182
20995	7590	08/04/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			NASSER, ROBERT L	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3736	

DATE MAILED: 08/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/758,495

Applicant(s)

SILVER ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 and 38-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/5/04 & 4/12/04</u> . | 6) <input type="checkbox"/> Other: ____ |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-37 and 41-48, drawn to a sensor for implantation in a blood vessel and method for minimizing thrombus formation of a sensor, classified in class 600, subclass 345.
- II. Claims 38-40, drawn to a method for retrieving an implantable sensor, classified in class 600, subclass 350.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as measuring glucose or another analyte in the body. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I, an implanted sensor to minimize thrombus formation.

Species II, drawn to an implanted sensor to measure nitric oxide.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. Irfan Lateef on July 14, 2005, a provisional election was made with traverse to prosecute the invention of Group I, species II, claims 25-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-24 and 38-48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner notes that none of the prior applications detect nitric oxide or a metabolite thereof. Accordingly, claims 25-37 have a filing date only of the current application, or January 15, 2004.

Claim Objections

Claim 31 is objected to in that there is no antecedent basis for the tubular support structure, as it was previously referred to only as a support structure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 27, 29, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Lebel et al 2004/0236201. Lebel et al shows a catheter having a sensing end comprising a sensor support 30 holding an electrochemical sensor, and a sensor housing 22, where the sensor is exposed to outside of the housing via an opening in the sidewall of the housing. The sensor is capable of sensing nitric oxide (see paragraph [0032]). Again, one may leave the catheter in the body as long as desired. With respect to claim 29, the sensor is on the luminal side of the support, depending on the orientation of the device, noting that applicant has not defined to what structure the lumen belongs.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25, 26, 28, and 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silver 6442413 in view of Lebel et al. Silver 6442413 qualifies as art under 102 (a) and (b) and hence is useable in a 103 rejection. Silver shows a glucose sensor housing having a sensing surface exposed to the blood, that is mounted on a stent, which is an expandable mesh. The device further has an eptfe coating on the outward side of the device. It does not sense nitric oxide or a metabolite thereof. However, Lebel teaches that the same device may measure either glucose or nitric

oxide. Hence, it would have been obvious to modify Silver to measure nitric oxide, as it is merely the substitution of one known analyte for another. Claims 34 and 35 are rejected in that Silver uses an amperometric or ion-selective electrode. With respect to claim 36, the device has an enzyme gel layer beneath a membrane (see Silver, column 5, lines 30-31).

Claims 34 and 35 are rejected under 35 USC 103(a) as being unpatentable over Lebel et al. The examiner takes official notice that both amperometric and ion-selective electrodes are well known analyte sensing electrodes. Hence, it would have been obvious to modify Lebel to use the such electrodes, as it is merely the substitution of one known equivalent electrode for another.

Claims 36 is rejected under 35 USC 103(a) as being unpatentable over Lebel et al in view of Schulman et al 6119028. Schulman further teaches that it is well known to have a membrane between the sensor and the internal environment to control what substances actual reach the sensor, to increase the sensor life. Hence, it would have been obvious to modify Lebel to use a membrane, to increase the lifetime of the sensor. Lebel already uses an enzyme. The examiner takes official notice that it is well known to provide such an enzyme as a gel.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silver in view of Lebel et al, as applied to claim 36 above, and further in view of Kaylor et al 2005/0101841. Kaylor et al further teaches that when detecting Nitrate, it is well known to use nitrate reductase as the enzyme. Hence, it would have been obvious to modify

the above combination to use nitrate reductase, as it is merely the substitution of one known equivalent enzyme for another.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al in view of Schulman, as applied to claim 36 above, and further in view of Kaylor et al 2005/0101841. Kaylor et al further teaches that when detecting Nitrate, it is well known to use nitrate reductase as the enzyme. Hence, it would have been obvious to modify the above combination to use nitrate reductase, as it is merely the substitution of one known equivalent enzyme for another.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Allen et al 6280604 shows a nitric oxide sensing electrode mounted on a catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
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RLN
July 29, 2005

A handwritten signature in black ink, appearing to read "Robert L. Nasser", with a stylized flourish at the end.

ROBERT L. NASSER
PRIMARY EXAMINER